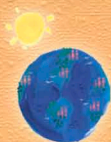
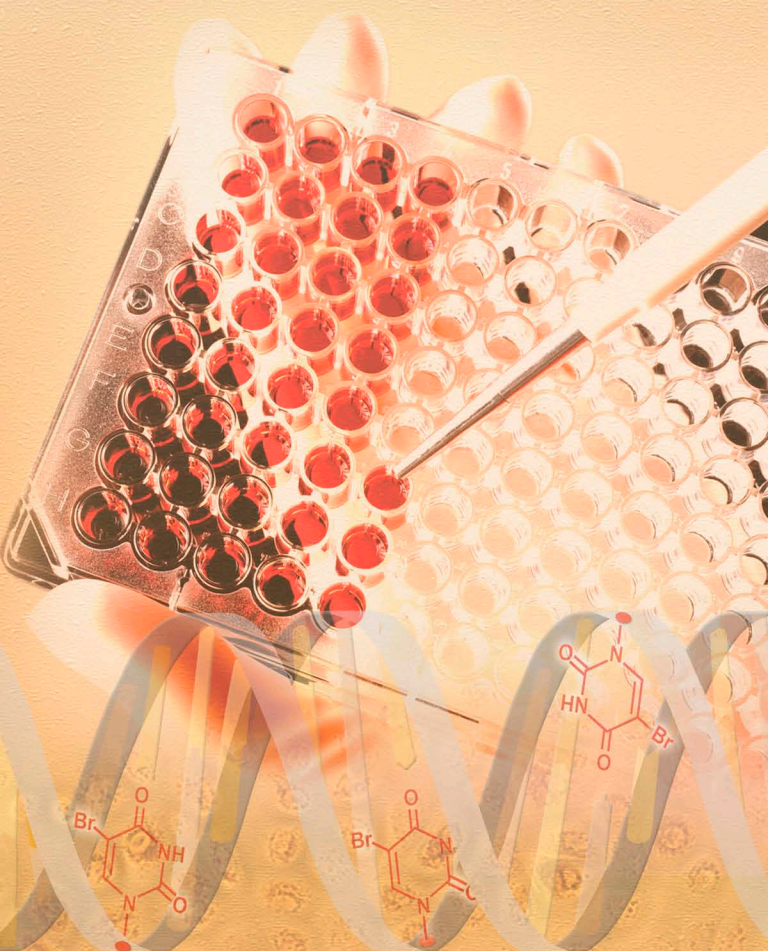


Nominations and Submissions to ICCVAM

A Guide for Test Method
Developers and Sponsors



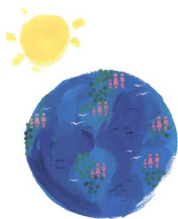
National Toxicology Program Interagency Center for the Evaluation
of Alternative Toxicological Methods
Interagency Coordinating Committee on the Validation
of Alternative Methods
National Institute of Environmental Health Sciences
Research Triangle Park, NC

NICEATM and ICCVAM carry out a wide range of activities, including test method validation studies and comprehensive evaluations, to promote the development, scientific validation, and regulatory acceptance of new, revised, and alternative safety testing methods. Accordingly, NICEATM and ICCVAM seek **nominations** and **submissions** of new or revised safety testing methods for validation studies or formal evaluations. Methods are especially sought that have the potential to:

- Reduce, refine, and/or replace the use of animals in testing
- Maintain and promote scientific quality and the protection of human health, animal health, and the environment

A test method **submission** consists of a proposal to ICCVAM for review and evaluation of a test method for which there are completed validation studies. After review, ICCVAM forwards test method recommendations to Federal agencies. Agencies use this information to determine the acceptability of the test method for their needs.

A test method **nomination** consists of a proposal to ICCVAM for activities relevant to the review or validation of specific test method(s) or to address relevant testing or validation issues. Nominations might consist of proposals for validation studies, workshops, peer reviews, or other appropriate activities.



The NICEATM-ICCVAM graphic symbolizes the important role of new and alternative toxicological methods in protecting and advancing the health of people, animals, and the environment.



What are NICEATM and ICCVAM?

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) is an interagency committee of the U.S. Government established by the ICCVAM Authorization Act of 2000 (Public Law 106-545, 42 U.S.C. 285I-3). ICCVAM's members include 15 Federal regulatory and research agencies that require, use, generate, or distribute safety testing information. Such information is used to protect workers and consumers from injuries or diseases that may result from exposure to hazardous chemicals and products.

ICCVAM coordinates interagency technical reviews of new and revised safety testing methods. The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies.

What kinds of test methods are eligible for ICCVAM evaluation?

Any new, revised, or alternative safety testing method with regulatory applicability is eligible for evaluation by ICCVAM. ICCVAM prioritizes test methods for evaluation using criteria that include:

- The potential for the proposed test method to improve the prediction of adverse health or environmental effects
- The potential for the alternative test method to reduce, refine (decrease pain or distress), or replace animal use
- The potential for the proposed test method to apply to regulations across multiple agencies

NICEATM and ICCVAM conduct test method evaluation activities in a number of areas. Currently, the four highest priority areas are ocular toxicity, dermal toxicity, acute toxicity, and biologics. Other areas of interest include dermal sensitization, endocrine disruption, reproductive/developmental toxicity, and chronic toxicity/carcinogenicity.



How do we prepare a nomination or submission to ICCVAM?

The *ICCVAM Guidelines for the Nomination and Submission of New, Revised, and Alternative Test Methods* (NIH Publication No. 03-4508; available on the NICEATM-ICCVAM web site) provides detailed guidance on preparing nominations and submissions of test methods for consideration by ICCVAM. Elements of a complete submission package include:

- Rationale for the proposed test method
- Test method protocol
- Substances used for validation of the proposed test method
- *In vivo* reference data used to assess the accuracy of the proposed test method
- Test method data and results
- Characterization of test method accuracy and reliability
- Assessment of test method data quality
- Animal welfare considerations (reduction, refinement, and replacement)

Complete submissions serve as a basis for assessing the validation status of a proposed test method through an independent ICCVAM peer review process.

Sponsors may nominate test methods for which a complete submission package is not available for evaluation by ICCVAM. These test methods may be evaluated in an expert workshop or become the basis for an international validation study sponsored by NICEATM.

NICEATM initially evaluates nominations or submissions to ICCVAM to assess the relevance of the nomination or the adequacy and completeness of the submission. ICCVAM then determines the priority the proposed test method will have for technical evaluation. Depending on the validation status of the proposed test method, ICCVAM, in conjunction with NICEATM, develops recommendations and priorities for further efforts. Such efforts might include an expert workshop, an evaluation with independent scientific peer review, or a validation study.



Can we get assistance in preparing our nomination or submission?

Yes. Sponsors are encouraged to consult with NICEATM and ICCVAM throughout the test method development and validation process, as well as during preparation of submissions. Such interactions will increase the likelihood that validation studies and submissions will adequately characterize the usefulness and limitations of the proposed test method. This adequate characterization will give agencies the information necessary to determine whether a test method can generate information that will meet their regulatory needs.

Does NICEATM sponsor validation studies?

Yes. NICEATM conducts and coordinates international validation studies to evaluate promising new alternative test methods that may reduce, replace, or refine animal use for toxicity testing and that may improve safety assessment for people, animals, and the environment. These studies are conducted in cooperation with NICEATM's international counterparts through an International Cooperation on Alternative Test Methods.

Are grants available for development of test methods?

Yes. NIEHS supports research and training focused on the identification, assessment and mechanism of action of agents in the environment and how they contribute to disease. This includes development, standardization, and validation of new and novel tests or batteries of tests that will provide faster and less expensive alternatives to the use of standard laboratory animal tests. Information about the NIEHS Small Business Innovation Research/ Small Business Technology Transfer grants program is available on the NIEHS website at: <http://www.niehs.nih.gov/research/supported/programs/sbir/>

ICCVAM Member Agencies:

(Member agencies are indicated in boldface)

- **Consumer Product Safety Commission**
- **Department of Agriculture**
- **Department of Defense**
- **Department of Energy**
- Department of Health and Human Services
 - Centers for Disease Control and Prevention
 - **Agency for Toxic Substances and Disease Registry**
 - **National Institute for Occupational Safety and Health**
 - **Food and Drug Administration**
 - National Institutes of Health
 - **Office of the Director**
 - **National Cancer Institute**
 - **National Institute of Environmental Health Sciences**
 - **National Library of Medicine**
- **Department of the Interior**
- Department of Labor
 - **Occupational Safety and Health Administration**
- **Department of Transportation**
- **Environmental Protection Agency**

More information about NICEATM and ICCVAM can be found on the NICEATM-ICCVAM web site:

<http://iccvam.niehs.nih.gov>

NICEATM encourages companies and organizations that wish to propose nominations or submissions of promising test methods to contact us for information and guidance on preparing proposals. Please contact us at:

Telephone: [919] 541-2384

E-mail: niceatm@niehs.nih.gov

